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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,283	02/26/2002	David R. Diduch	DID-101	7097
36013 7590 01/12/2009 MOAZZAM & ASSOCIATES, LLC 7601 LEWINSVILLE ROAD SUITE 304 MCLEAN, VA 22102				
EXAMINER				
OU, JING RUI				
ART UNIT		PAPER NUMBER		
3773				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/084,283

Applicant(s)

DIDUCH ET AL.

Examiner

JING OU

Art Unit

3773

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50, 53, 56, 57, 59-62 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50, 53, 56, 57, 59-62 and 65-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 50, 53, 56, 57, 59-62, and 65-67 are pending.

Specification

2. The disclosure is objected to because of the following informalities: Examiner cannot find support for recitation “the opening in the jaw is partially open” of claims 56, 60, and 65 in the disclosure.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 56, 60, and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitations, “the opening in the jaw is partially open” in claims 56, 60, and 65 are unclear. Examiner cannot find support for such recitation in the disclosure. An opening is open, not partially open. The specification discloses a thin edge extends partially or completely around the upper jaw profile. In addition, it is unclear and confusing how the jaw is removable from around a side of a strand of suture that has been passed into the soft tissue.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 50, 59, 60, 62, 65, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Caspari et al (US Pat. No.: 4,923,461).

In regard to Claims 50, 59, 60, 62, 65, and 67, Caspari et al discloses a surgical device (suturing instrument, 20, Fig. 1) for passing suture through soft tissue, comprising: a body (elongate tube, 36, Fig. 1) having a lumen to accommodate an elongate member (combination of tubing 104 and needle 56, Figs 5 and 6 and Col. 4, lines 19-22) having a puncturing projection (needle, 56, Fig. 5); a grasping mechanism comprising a first jaw (44, Fig. 2) and second jaw (34, Fig. 2) connected to said body and encompassing at least a portion of the elongate member, one of the jaws moveable relative to the other and having an opening (65, Fig. 1) at the middle region of the jaw to receive at least one strand of suture for allowing the elongate member therethrough and to the soft tissue, and wherein said grasping mechanism clamps soft tissue while the suture passing member slides within the lumen and passes suture through the soft tissue outside of the grasping mechanism through an opening in one of said jaws of said grasping mechanism (Figs. 11-12 and Col. 4, lines 59-68); the puncturing projection (needle, 56, Fig. 5) having a distal portion and carrying a suture (Col. 5, lines 1-5, the needle has an opening at its distal end and carries a suture when the suture passes through the distal opening of the needle), the puncturing projection movable between a first position wherein the distal portion of the puncturing projection is substantially contained within an area between the first jaw and the second jaw and a second position wherein the distal portion of the puncturing projection extends beyond

the first jaw (Col. 3, lines 57 and Figs 1 and 11-15); and a handle (26, Fig. 2) to manipulate movement of the jaws.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 61 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caspari et al (US Pat. No.: 4,923,461).

In regard to Claims 61 and 66, Caspari et al discloses all the limitations of the claims but fails to disclose the first elongated member comprises an eyelet. However, it is old and well known in the art that an elongated tissue-puncturing member / a suturing passing member / a needle has an eyelet to carry or manipulate a suture strand. Therefore, it would have been obvious to modify the needle of Caspari et al to include an eyelet for carrying and manipulating the suture.

11. Claims 53, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caspari et al (US Pat. No.: 4,923,461) in view of Middleman et al (US Pat. No.:5,820,628).

In regard to Claims 53, 56, and 57, Caspari et al discloses a surgical device (suturing instrument, 20, Fig. 1) for passing suture through soft tissue, comprising: a grasping mechanism comprising a first jaw (44, Fig. 2) and second jaw (34, Fig. 2) connected to said body and encompassing at least a portion of the elongate member, one of the jaws moveable relative to the other and having an opening (65, Fig. 1) at the middle region of the jaw to receive at least one strand of suture for allowing the elongate member therethrough and to the soft tissue, and wherein said grasping mechanism clamps soft tissue while the suture passing member slides within the lumen and passes suture through the soft tissue outside of the grasping mechanism through an opening in one of said jaws of said grasping mechanism (Figs. 11-12 and Col. 4, lines 59-68); a second elongate member (elongate tube, 36, Fig. 1) having a lumen to accommodate a

first elongate member (combination of tubing 104 and needle 56, Figs 5 and 6 and Col. 4, lines 19-22).

Caspari et al does not appear to disclose that the first elongate member has a first resting configuration, second stressed configuration and an eyelet.

However, Middleman et al explicitly discloses a needle/elongate member has a first resting configuration (curved configuration, Fig. 15C) and is compressible into a second, stressed configuration (relatively straight configuration, 15A), and returns towards said first resting configuration as a compressive external force is reduced (Figs. 15A-C and Col. 26, lines 26-40).

It is old and well-known in the art to include a needle having the abilities of obtaining a compressed configuration in a delivery tube and return to its resting configuration outside the delivery tube. The motivation/suggestion for do so would have been easier to deliver such needle within a straight elongate body to a target site in the human body. In addition, it is old and well known in the art that a needle has an eyelet to carry or manipulate a suture strand. Therefore, it would have been obvious to modify the needle of Caspari et al to include an eyelet for carrying and manipulating the suture.

Response to Arguments

12. Applicant's arguments filed 10/24/2008 have been fully considered but they are not persuasive. In regard to the 112 issue discussion on page 6 of the remarks, the recitations "the opening in the jaw is partially open" in claims 56, 60, and 65 are unclear. Examiner cannot find support for such recitation in the disclosure. An opening is open,

not partially open. The specification discloses a thin edge extends partially or completely around the upper jaw profile. In addition, it is unclear and confusing how the jaw is removable from around a side of a strand of suture that has been passed into the soft tissue.

The allegation on page 7-9 of the remarks that Caspari does not disclose or suggest a puncturing projection movable between a first position and a second position is incorrect. Caspari discloses the puncturing projection movable between a first position wherein the distal portion of the puncturing projection is substantially contained within an area between the first jaw and the second jaw and a second position wherein the distal portion of the puncturing projection extends beyond the first jaw (Col. 3, lines 46-57 and Figs 1 and 11-15). Although the puncturing projection 56 of Caspari may be firmly attached to the lower jaw and not flexible, the movement of the puncturing projection 56 from the first position to the second position does not necessarily be relative to the device.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fuchs et al (US Pat. No.: 5,980,538) and Nolan et al (EP 0812572 A1)

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

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